



[3510-16-P]

**DEPARTMENT OF COMMERCE**

**United States Patent and Trademark Office**

**37 CFR Part 1**

[Docket No.: PTO-P-2011-0014]

**RIN 0651-AC56**

**Revision of Patent Term Adjustment Provisions Relating to Information**

**Disclosure Statements**

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Final rule.

**SUMMARY:** The United States Patent and Trademark Office (Office) is revising the patent term adjustment provisions of the rules of practice in patent cases. The patent term adjustment provisions of the American Inventors Protection Act of 1999 (AIPA) provide for a reduction of any patent term adjustment if the applicant failed to engage in reasonable efforts to conclude prosecution of the application. The Office is revising the rules of practice pertaining to the reduction of patent term adjustment

for applicant delays to exclude information disclosure statements resulting from the citation of information in a counterpart application that are promptly filed with the Office. The rule change allows the diligent applicant to avoid patent term adjustment reduction for an IDS submission that results from a communication from the Office. Presently, the rule only provides relief if the IDS was cited as a result of a communication from a foreign patent office. Under this final rule, there will be no reduction of patent term adjustment in the following situations: when applicant promptly submits a reference in an information disclosure statement after the mailing of a notice of allowance if the reference was cited by the Office in another application, or when applicant promptly submits a copy of an Office communication (e.g., an Office action) in an information disclosure statement after the mailing of a notice of allowance if the Office communication was issued by the Office in another application or by a foreign patent office in a counterpart foreign application. The above changes are intended to ensure compliance with AIPA in light of the evolving case law.

**EFFECTIVE DATE:** [Insert date of publication in the FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Kery A. Fries, Senior Legal Advisor, Office of Patent Legal Administration, by telephone at 571-272-7757, by mail addressed to: Box Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450, marked to the attention of Kery A. Fries.

**SUPPLEMENTARY INFORMATION:** The AIPA amended 35 U.S.C. 154(b) to provide patent term adjustment for certain delays during the patent examination process. See Pub. L. 106–113, 113 Stat. 1501, 1501A–552 through 1501A–591 (1999)). Specifically, under the patent term adjustment provisions of 35 U.S.C. 154(b) as amended by the AIPA, an applicant is entitled to patent term adjustment for the following reasons: (1) if the Office fails to take certain actions during the examination and issue process within specified time frames (35 U.S.C. 154(b)(1)(A)); (2) if the Office fails to issue a patent within three years of the actual filing date of the application in the United States (35 U.S.C. 154(b)(1)(B)); and (3) for delays due to interference, secrecy order, or successful appellate review (35 U.S.C. 154(b)(1)(C)). The AIPA, however, sets forth a number of conditions and limitations on any patent term adjustment accrued under 35 U.S.C. 154(b)(1). Specifically, 35 U.S.C. 154(b)(2)(C) provides, in part, that “[t]he period of adjustment of the term of a patent under [35 U.S.C. 154(b)(1)] shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application” and that “[t]he Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” 35 U.S.C. 154(b)(2)(C)(i) and (iii). The Office implemented the patent term adjustment provisions of 35 U.S.C. 154(b) as amended by the AIPA, including setting forth the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application, in a final rule published in September of 2000. See Changes to Implement Patent

Term Adjustment Under Twenty-Year Patent Term, 65 FR 56366 (Sept. 18, 2000)  
(patent term adjustment final rule).

Section 1.704(c) provides that the submission of an information disclosure statement either that is after a notice of allowance, an initial reply, or that requires a supplemental Office action, results in a reduction of any patent term adjustment under 37 CFR 1.703. See 37 CFR 1.704(c)(6), 1.704(c)(8), 1.704(c)(9), and (c)(10).

Section 1.704(d) provides that an information disclosure statement will not result in a patent term adjustment reduction under 37 CFR 1.704(c)(6), 1.704(c)(8), 1.704(c)(9), or (c)(10) if it is accompanied by a statement that each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement. 37 CFR 1.704(d) permits applicants to submit information first cited in a communication from a foreign patent office in a counterpart application to the Office without a reduction in patent term adjustment if an information disclosure statement is promptly (within thirty-days of receipt of the communication) submitted to the Office.

Recent decisions by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) underscore the importance of making information cited and Office actions issued in related copending foreign and domestic applications of record. See Dayco Products, Inc. v. Total Containment, Inc., 329 F.3d 1358 (Fed. Cir. 2003) and McKesson Info. Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897 (Fed. Cir.

2007); see also Larson Mfg. Co. v. Aluminart Products Ltd., 559 F.3d 1317 (Fed. Cir. 2009) (relating to disclosure in a U.S. reexamination proceeding of U.S. Office actions that were issued in a continuation application of the patent under reexamination). The Office is revising 37 CFR 1.704(d) to also embrace information first cited in a communication from the Office, as well as the communication (e.g., Office action) in a counterpart foreign or international application. These revisions are intended to ensure compliance with AIPA in light of the evolving case law. Obviously, meeting the conditions set forth in 37 CFR 1.704(d) does not substitute for compliance with any relevant requirement of 37 CFR 1.97 or 1.98.

### **Discussion of Specific Rules**

Title 37 of the Code of Federal Regulations, Part 1, is amended as follows:

Section 1.704: Section 1.704(d) is amended to change “any communication from a foreign patent office in a counterpart application” to “any communication from a patent office in a counterpart foreign or international application or from the Office,” and to add to this definition “a communication that was issued by a patent office in a counterpart foreign or international application or by the Office.” This change revises § 1.704(d) to also embrace information first cited in a communication from the Office, as well as the communication (e.g., Office action) in a counterpart foreign or international application or from the Office itself.

**Response to Comments:** The Office published a notice in April of 2011 proposing to change the rules of practice pertaining to patent term extension and adjustment to: (1) indicate that in most circumstances an examiner reopening prosecution of the application after a notice of appeal has been filed will be considered a decision in the review reversing an adverse determination of patentability for purposes of patent term adjustment or extension purposes; and (2) exclude information disclosure statements resulting from the citation of information by a foreign patent office in a counterpart application that are promptly filed with the Office from the provisions for the reduction of patent term adjustment for applicant delays. See Revision of Patent Term Extension and Adjustment Provisions Relating to Appellate Review and Information Disclosure Statements, 76 FR 18990 (Apr. 6, 2011). The Office received eight written comments in response to this notice. The Office is revising its proposal concerning the reopening of prosecution of an application by the Office after a notice of appeal has been filed and will publish that proposal for public comment in a separate rule making. The comments and the Office's responses to the comments pertaining to information disclosure statements resulting from the citation of information by a foreign patent office in a counterpart application that are promptly filed with the Office follow.

The comments on the Office's proposed change to 37 CFR 1.704(d) pertaining to information disclosure statements supported the proposed change. The Office also received comments on provisions of 37 CFR 1.704 that the Office did not propose to change: (1) one comment suggested changing the thirty day to a three month period;

and (2) one comment indicated that an information disclosure statement filed after a notice of appeal should not result in reduction under 37 CFR 1.704(c)(8).

The Office did not propose to change the thirty-day period in 37 CFR 1.704(d). The Office adopted the provisions of 37 CFR 1.704(d) in 2000 to permit applicants to avoid a patent term adjustment impact if an information disclosure statement containing information that was cited in a communication from a foreign patent office in a counterpart application is promptly submitted to the Office. The Office does not consider an information disclosure statement filed more than thirty days after the information has been brought to applicant's attention to be promptly submitted.

Regarding the second comment, 37 CFR 1.704(c)(8) does not provide for a reduction of any patent term adjustment simply because an applicant files an information disclosure statement after a notice of appeal has been filed.

#### **Rule Making Considerations:**

**A. Regulatory Flexibility Act:** For the reasons set forth herein, the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that the changes in this rule making will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

This rule making expands the exception to the patent term adjustment reduction for filing an information disclosure statement after a notice of allowance or reply, or for filing an information disclosure statement that requires a supplemental Office action, for information cited by a foreign patent office in a counterpart application that is promptly filed with the Office, to embrace information first cited by the Office in another application. This rule making does not add any additional requirements (including information collection requirements) or fees for patent applicants or patentees. Therefore, the changes in this rule making will not have a significant economic impact on a substantial number of small entities.

**B. Executive Order 12866 (Regulatory Planning and Review):** This rule making has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

**C. Executive Order 13563 (Improving Regulation and Regulatory Review):** The Office has complied with Executive Order 13563. Specifically, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector and the public as a whole, and provided on-line



access to the rule making docket; (7) attempted to promote coordination, simplification and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

**D. Executive Order 13132 (Federalism):** This rule making does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

**E. Executive Order 13175 (Tribal Consultation):** This rule making will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

**F. Executive Order 13211 (Energy Effects):** This rule making is not a significant energy action under Executive Order 13211 because this rule making is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

**G. Executive Order 12988 (Civil Justice Reform):** This rule making meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

**H. Executive Order 13045 (Protection of Children):** This rule making does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

**I. Executive Order 12630 (Taking of Private Property):** This rule making will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

**J. Congressional Review Act:** Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), prior to issuing any final rule, the United States Patent and Trademark Office will submit a report containing the final rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the Government Accountability Office. The changes in this notice are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this notice is not expected to result in a “major rule” as defined in 5 U.S.C. 804(2).

**K. Unfunded Mandates Reform Act of 1995:** The changes in this rule making do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 et seq.

**L. National Environmental Policy Act:** This rule making will not have any effect on the quality of environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 et seq.

**M. National Technology Transfer and Advancement Act:** The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rule making does not contain provisions which involve the use of technical standards.

**N. Paperwork Reduction Act:** The rules of practice pertaining to patent term adjustment and extension have been reviewed and approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) under OMB control number 0651-0020. As discussed

previously, this rule making expands the exception to the patent term adjustment reduction for filing an information disclosure statement after a notice of allowance or a reply, or for filing an information disclosure statement that requires a supplemental Office action, for information cited by a foreign patent office in a counterpart application that are promptly filed with the Office, to embrace information first cited by the Office in another application. This notice does not propose to add any additional requirements (including information collection requirements) or fees for patent applicants or patentees. Therefore, the Office is not resubmitting information collection packages to OMB for its review and approval because the changes in this rule making do not affect the information collection requirements associated with the information collections approved under OMB control number 0651-0020.

Notwithstanding any other provision of law, no person is required to respond to nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

#### **List of Subjects in 37 CFR Part 1**

Administrative practice and procedure, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons set forth in the preamble, 37 CFR part 1 is amended as follows:

## **PART 1 - RULES OF PRACTICE IN PATENT CASES**

1. The authority citation for 37 CFR Part 1 continues to read as follows:

**Authority:** 35 U.S.C. 2(b)(2).

2. Section 1.704 is amended by revising paragraph (d) to read as follows:

### **§ 1.704 Reduction of period of adjustment of patent term.**

\* \* \* \* \*

(d)(1) A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement:

(i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or

(ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not

received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

(2) The thirty-day period set forth in paragraph (d)(1) of this section is not extendable.

\* \* \* \* \*

Date: \_November 21, 2011\_

---

David J. Kappos  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office

[FR Doc. 2011-30933 Filed 11/30/2011 at 8:45 am; Publication Date: 12/01/2011]